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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/672,586

09/26/2003

John D. Puskas

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EXAMINER

MULLEN, KRISTEN DROESCH

ART UNIT

PAPER NUMBER

3766

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
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3 MONTHS

01/11/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/672,586

Applicant(s)

PUSKAS, JOHN D.

Examiner

Kristen Mullen

Art Unit

3766

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 December 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 46-59, 131-144, 149 and 150 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 131-144 is/are allowed.
- 6) ☒ Claim(s) 46-59, 149 and 150 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 September 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Allowable Subject Matter

1. The indicated allowability of claims 46-59 is withdrawn in view of the newly discovered reference(s) to Matheny (5,561,378). Rejections based on the newly cited reference(s) follow.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

3. Claims 46-47, 51-52, 59 and 149 are rejected under 35 U.S.C. 102(a) as being anticipated by Matheny et al. (5,651,378).

With respect to claim 46, Matheny teaches a method including actuating an electrode to create an electrical field effective to stimulate a vagus nerve to achieve controlled asystole (Col. 1, lines 66-Col. 2, line (Col. 3, lines 42-49) and also teaches that the stimulator may be of the type disclosed in U.S. Pat. No. 5,458,625 (external stimulator that has an electrode that clips onto the body) and may be attached to the patient's neck (Col. 4, lines 6-11).

Regarding claim 47 and 149, Matheny, by effective incorporation by reference of U.S. Pat. No. 5,458,625, shows the stimulator includes two electrodes (54, 56) that are spaced apart from one another (Figs. 2-3), therefore when Matheny applies the stimulator structure of U.S. Pat. No. 5,458,625 to the neck, Matheny will be positioning a first electrode and second electrode on the neck of the patient with the second electrode in spaced apart relation to the first electrode.

Art Unit: 3766

Regarding claims 51-52, Matheny shows the vagus nerve is stimulated for five seconds (Col. 2, lines 7-9).

With respect to claim 59, Matheny shows the vagus nerve is stimulated during minimally invasive coronary bypass surgery.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

5. Claims 48 and 150 is rejected under 35 U.S.C. 103(a) as being unpatentable over Matheny et al. (5,651,378) as applied to claims 47 and 149 above and further in view of by Hill et al. (RE 38,705). Matheny fails to explicitly teach that the second electrode is positioned approximately one centimeter from the first electrode. Attention is directed to Hill who teaches that the spacing between the first and second electrodes for vagal stimulation to effect asystole can vary depending upon among other things the size of the vagus nerve and the amount of current applied (Col. 7, lines 46-49). It would have been obvious to one with ordinary skill in the art at the time of the invention to position the second electrode from the first electrode by approximately one centimeter since the positioning of the electrodes is a result effective variable that can be determined by routine experimentation by one with ordinary skill in the art. It has been held by our reviewing courts that it is within the level of ordinary skill in the art to discover an optimum value of a result effective variable. See MPEP 2144.05 and *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA, 1980).

Art Unit: 3766

6. Claims 49-50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matheny et al. (5,651,378) as applied to claim 47 above and in further view of Taylor et al. (5,913,876).

Although Matheny fails to explicitly show that creating an electrical field comprising actuating both of the first and second electrode (i.e. bipolar stimulation), attention is directed to Taylor who teaches that bipolar stimulation is more efficient than unipolar vagal stimulation (Col. 11, lines 9-13). It would have been obvious to one with ordinary skill in the art at the time the invention was made to modify the method of Matheny to include creating an electrical field comprising actuating both of the first and second electrode since Taylor teaches that bipolar stimulation is more efficient than unipolar stimulation.

7. Claims 53- 58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Matheny et al. (5,651,378).

Matheny discloses the claimed invention except for applying an electrical impulse with a frequency of between one Hz and 500 Hz, between 20 Hz and 80 Hz, or about 40 Hz, a impulse duration of about 0.4 msec, an impulse amplitude from one V to 40 V or two V to six V.

Matheny teaches that the appropriate amount of electrical energy needed to achieve the desired result can be readily determined empirically once the type of equipment and point of access are known. It would have been an obvious design choice to one with ordinary skill in the art at the time the invention was made to modify the electrical impulse amplitude as taught by Matheny with an electrical impulse having an a frequency of between one Hz and 500 Hz, between 20 Hz and 80 Hz, or about 40 Hz, a impulse duration of about 0.4 msec, an impulse amplitude from one V to 40 V or two V to six V since applicant has not disclosed that this amplitude of electrical impulse provides any criticality and /or unexpected results and it appears that the invention

Art Unit: 3766

would perform equally well with the electrical impulse parameters disclosed by Matheny for stimulating the vagus nerve to achieve controlled asystole.

Allowable Subject Matter

8. Claims 131-144 are allowed.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kristen Mullen whose telephone number is (571) 272-4944. The examiner can normally be reached on M-F, 10:30 am-6:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



Kristen D. Mullen
Patent Examiner
Temp. Full Signatory Authority
Art Unit 3766

kdm